UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

PROVEPHARM, INC.

Plaintiff,

v.

AKORN, INC.,

Defendant.

CIVIL ACTION NO. 17-CV-7087--ADS-AKT

AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF AKORN, INC.

JURY DEMAND

Pursuant to the parties' May 30, 2018 joint letter to the Court (Dkt. No. 32) setting August 27, 2018, as the final date to amend pleadings, Defendant Akorn, Inc., ("Akorn" or "Defendant") hereby amends its Answer to the Complaint of Plaintiff Provepharm, Inc. ("Provepharm" or "Plaintiff") and counterclaims as follows:

NATURE AND BASIS OF THE ACTION

1. Akorn admits that the Complaint concerns Provepharm's ProvayBlue® methylene blue injection USP ("ProvayBlue®"). Akorn denies the allegations of this paragraph that "Defendant's efforts to take ProvayBlue® sales through a campaign of false and misleading advertising." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore denies same.

2. Akorn denies the allegations of this paragraph.

3. Akorn denies that its product is "substandard." Akorn denies the allegations of this paragraph.

4. Akorn denies that it makes false and misleading statements, that it makes false and misleading advertising claims, and that it harmed Provepharm. The remaining averments of paragraph 4 are Plaintiff's characterization of the remedies that it seeks, and as such do not

require a response, except that Akorn denies that Plaintiff is entitled to injunctive relief, damages, or any other relief.

PARTIES

5. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore denies the same.

6. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore denies the same.

7. Akorn admits that it is a corporation organized and existing under the laws of Louisiana, having a place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045. Akorn also admits that it has a facility in Amityville, NY. Akorn admits that it is registered to do business in New York. Akorn also admits that its designated Registered Agent is Corporation Service Company, 501 Louisiana Avenue, Baton Rouge, Louisiana 70802. Akorn also admits that its website www.akorn.com states, "Akorn, Inc. is a niche pharmaceutical company that develops, manufactures and markets generic and branded prescription pharmaceuticals as well as animal and consumer health products." Akorn denies any remaining allegations of this paragraph.

JURISDICTION AND VENUE

8. This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn admits that this Court has subject-matter jurisdiction on claims brought pursuant to 28 U.S.C. §§ 1331 & 1338(a) and 15 U.S.C. §§ 1116 & 1121. Akorn denies that this Court has subject matter jurisdiction over any other claims asserted herein. Akorn denies any remaining allegations of this paragraph.

9. This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn lacks knowledge or sufficient information to form a

belief as to the applicability of 28 U.S.C. § 1367 and the doctrine of supplemental jurisdiction to Plaintiff's state law claims, and therefore denies the same.

10. This paragraph states legal conclusions to which no answer is required. To the extent an answer is deemed required, Akorn does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Akorn denies any remaining allegations of this paragraph.

11. This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn does not contest venue in this district for purposes of this action only.

FACTUAL BACKGROUND

A. ProvayBlue® Safely and Effectively Treats Methemoglobinemia

12. Akorn does not dispute Plaintiff's statement in paragraph 12, which generally defines the medical condition of methemoglobinemia. By way of further response, Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegation that "ProvayBlue Safely and Effectively Treats Methemoglobinemia" used in the heading for Section A, and therefore, denies those allegations.

13. Akorn does not dispute Plaintiff's statement in paragraph 13, which generally describes the medical condition of methemoglobinemia.

14. Akorn does not dispute Plaintiff's statement in paragraph 14, which generally describes the use of methylene blue as both a dye and a medication to treat methemoglobinemia.

15. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore denies those allegations.

16. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

B. The FDA Approves ProvayBlue®

17. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

18. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

19. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

20. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

21. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

22. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

23. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

24. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

25. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

26. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

27. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

C. The USP Adopts the High Standards Established by ProvayBlue®

28. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations in paragraph 28, and therefore, denies those allegations. By way of further response, Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations regarding the "High Standards Established by ProvayBlue" used in the heading for Section C, and therefore, denies those allegations.

29. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

30. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

31. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

D. Akorn's Unapproved and Substandard Methylene Blue Injection

32. Akorn admits that it is not affiliated with Provepharm. Akorn denies the allegations made in the heading for Section D.

33. Akorn admits that its website www.akorn.com states, "Akorn, Inc. is a niche pharmaceutical company that develops, manufactures and markets generic and branded prescription pharmaceuticals as well as animal and consumer health products. We specialize in difficult-to-manufacture sterile and non-sterile dosage forms including: ophthalmics, injectables, oral liquids, optics, topicals, inhalants, and nasal sprays." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

34. Akorn admits that it began marketing methylene blue in 2009. Akorn's package insert for methylene blue speaks for itself. Akorn lacks knowledge or sufficient information to

form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

35. Akorn denies the allegations of this paragraph.

36. Akorn denies that its product is "substandard." The methylene blue label and package insert speak for themselves. Akorn denies the remaining allegations of this paragraph.

37. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

38. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

39. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

E. Akorn Falsely Advertises Its Substandard Product as a 1% Methylene Blue Solution Compliant with USP Standards

40. Akorn denies that its product is "substandard." Akorn denies the allegations of paragraph 40. By way of further response, Akorn denies the allegations made in the heading for Section E.

41. Akorn denies that its product is "substandard." Akorn denies the allegations of this paragraph.

42. This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it makes false and misleading statements.

43. This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it makes false statements. Akorn also denies that its product is "substandard." Akorn lacks knowledge or sufficient information to

form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies these allegations.

44. This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies the allegations of this paragraph.

45. This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it makes false and misleading statements. Akorn also denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies these allegations.

46. This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it makes false and misleading statements. Akorn also denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies these allegations.

47. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

48. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations**.**

F. Akorn Falsely Advertises Its Substandard Product as Safer than ProvayBlue®

49. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations. By way of further response, Akorn denies the allegations made in the heading to Section F.

50. Akorn denies that its product is "substandard." Akorn denies Plaintiff's allegation that, "Akorn implicitly and necessarily communicates the message that the Akorn Substandard Product is safer than ProvayBlue®." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

51. This paragraph states legal conclusions to which no response is required. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

52. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

53. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

G. Akorn Falsely Advertises Its Substandard Product as FDA Approved

54. Akorn denies that its product is "substandard." Akorn denies the allegations of this paragraph. By way of further response, Akorn denies the allegations made in the heading to Section G.

55. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

56. Akorn denies the allegations of this paragraph.

57. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

58. Akorn denies that its product is "substandard." This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it makes false statements. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

59. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

60. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

H. Akorn's False and Misleading Advertising Succeeded in Taking Sales Away From Provepharm

61. Akorn denies that its product is "substandard." This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it engages in false and misleading advertising and promotion. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations. By way of further response, Akorn denies the allegations made in the heading of Section H.

62. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

63. Akorn denies that its product is "substandard." This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it engages in false and misleading advertising or that it deceived customers.

Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

64. Akorn denies that its product is "substandard." This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it has engaged in false and/or misleading advertising. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

65. This paragraph states legal conclusions to which no response is required. To the extent a response is deemed required, Akorn denies that it has engaged in false and/or misleading advertising. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

66. Akorn denies that its product is "substandard." Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's remaining allegations, and therefore, denies those allegations.

COUNT I
FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT, 15 U.S.C. § 1125(a)

67. In response to paragraph 67 of the Complaint, Akorn incorporates by reference its responses to paragraphs 1-67 above as if fully stated herein.

68. Akorn denies the allegations of this paragraph.

69. Akorn denies the allegations of this paragraph.

70. Akorn denies the allegations of this paragraph.

71. Akorn denies the allegations of this paragraph.

72. Akorn denies the allegations of this paragraph.

73. Akorn denies the allegations of this paragraph.

74. Akorn denies the allegations of this paragraph.

75. Akorn denies the allegations of this paragraph.

76. Akorn denies the allegations of this paragraph.

77. Akorn denies the allegations of this paragraph.

COUNT II
UNFAIR COMPETITION IN VIOLATION OF THE LANHAM ACT, 15 U.S.C. § 1125(a)

78. In response to paragraph 78 of the Complaint, Akorn incorporates by reference its responses to paragraphs 1-78 above as if fully stated herein.

79. Akorn lacks knowledge or sufficient information to form a belief as to the truth of Plaintiff's allegations, and therefore, denies those allegations.

80. Akorn denies the allegations of this paragraph.

81. Akorn denies the allegations of this paragraph.

82. Akorn denies the allegations of this paragraph.

COUNT III
COMMON LAW UNFAIR COMPETITION

83. In response to paragraph 83 of the Complaint, Akorn incorporates by reference its responses to paragraphs 1-83 above as if fully stated herein.

84. Akorn denies the allegations of this paragraph.

85. Akorn denies the allegations of this paragraph.

86. Akorn denies the allegations of this paragraph.

87. Akorn denies the allegations of this paragraph.

88. Akorn denies the allegations of this paragraph.

89. Akorn denies the allegations of this paragraph.

COUNT IV
DECEPTIVE TRADE PRACTICES IN VIOLATION OF N.Y. GEN BUS. LAW §349(H)

90. In response to paragraph 90 of the Complaint, Akorn incorporates by reference its responses to paragraphs 1-90 above as if fully stated herein.

91. Akorn denies the allegations of this paragraph.

92. Akorn denies the allegations of this paragraph.

93. Akorn denies the allegations of this paragraph.

94. Akorn denies the allegations of this paragraph.

95. Akorn denies the allegations of this paragraph.

COUNT IV
FALSE ADVERTISING IN VIOLATION OF N.Y. GEN BUS. LAW §350(E)(3)

96. In response to paragraph 96 of the Complaint, Akorn incorporates by reference its responses to paragraphs 1-96 above as if fully stated herein.

97. Akorn denies the allegations of this paragraph.

98. Akorn denies the allegations of this paragraph.

99. Akorn denies the allegations of this paragraph.

100. Akorn denies the allegations of this paragraph.

101. Akorn denies the allegations of this paragraph.

PRAYER FOR RELIEF

Akorn denies that Plaintiff is entitled to any of the relief requested in its prayer for relief or any relief whatsoever.

AFFIRMATIVE DEFENSES

Akorn denies all allegations not expressly admitted herein. Without prejudice to the responses and denials set forth in Akorn's Amended Answer to the Complaint, and without

admitting any allegations of the Complaint not otherwise admitted, Akorn asserts the following defenses:

FIRST AFFIRMATIVE DEFENSE

Provepharm is barred from obtaining any relief sought in the Complaint because it has failed to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Akorn has acted in good faith in all of its marketing and/or advertising practices, in particular regarding its methylene blue injection product. Akorn acted in good faith and with a proper purpose to provide honest and truthful information and to protect the welfare of others.

THIRD AFFIRMATIVE DEFENSE

Provepharm's claims, or some of them, are barred because the Akorn's conduct with respect to its methylene blue injection product was permitted and/or authorized. Provepharm's claims, or some of them, are barred because the statements and actions by Akorn complained of by Provepharm were made and taken in connection with administrative proceedings in which Akorn was participating.

FOURTH AFFIRMATIVE DEFENSE

Provepharm's claims, or some of them, are barred by the doctrines of fair use and/or estoppel.

FIFTH AFFIRMATIVE DEFENSE

Provepharm's state law claims are barred to the extent they are preempted by federal law.

SIXTH AFFIRMATIVE DEFENSE

Provepharm's claims, or some of them, are barred by the First Amendment.

SEVENTH AFFIRMATIVE DEFENSE

Provepharm's claims for injunctive relief are barred to the extent Provepharm has an adequate remedy at law.

EIGHTH AFFIRMATIVE DEFENSE

Provepharm's claims, or some of them, are barred because Provepharm has suffered no damages.

NINTH AFFIRMATIVE DEFENSE

Provepharm's claims, or some of them, are barred because the statements and actions by Akorn complained of by Plaintiff were not false but true.

TENTH AFFIRMATIVE DEFENSE

Provepharm is not entitled to any relief under the doctrine of unclean hands. Provepharm seeks relief based on alleged false advertising by Akorn regarding the quality and content of its methylene blue drug product. Provepharm has falsely advertised its own methylene blue drug product, marketed under the tradename ProvayBlue.

RESERVATION OF DEFENSES

Additional facts may be revealed through the discovery process that support additional affirmative defenses that are currently unknown to Akorn. Therefore, Akorn reserves the right to assert additional affirmative defenses in the event that discovery (or its own investigation) supports the pleading of additional affirmative defenses.

WHEREFORE, defendant Akorn, Inc. requests that the Complaint be dismissed with prejudice, that judgment be entered in favor of Akorn, Inc. and against Provepharm, Inc., and that Akorn be awarded the costs of suit, including reasonable attorneys' fees, and such other and further relief as the Court may deem appropriate.

COUNTERCLAIM

1. For its counterclaim against Provepharm, Inc. ("Provepharm"), Akorn, Inc. ("Akorn") alleges as follows:

PARTIES

2. Counterclaim Plaintiff Akorn is a corporation organized and existing under the laws Louisiana, having a place of business 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045.

3. Upon information and belief, counterclaim defendant Provepharm is a corporation organized under the laws of Delaware with a principal place of business in Jericho, NewYork. Provepharm is the U.S. subsidiary of Provepharm Life Solutions based in Marseille, France.

JURISDICTION AND VENUE

4. Akorn and Provepharm are engaged in interstate commerce and in activities substantially affecting interstate commerce. They are engaged in a regular, continuous, and substantial flow of interstate commerce. Provepharm is a competitor of Akorn in connection with the sale of methylene blue injection products in the United States. The methylene blue injection products are sold in all fifty states and have a substantial effect upon interstate commerce.

5. This Court has federal question subject matter jurisdiction over the claims of this Complaint under the Sherman Act, 15 U.S.C. § 2, the Clayton Act, 15 U.S.C. § 15(a), 28 U.S.C. §1331, and as a civil action relating to the regulation of monopolies, 28 U.S.C. § 1337. This Court additionally has diversity jurisdiction and supplemental jurisdiction over closely related state law claims concerning unfair competition pursuant to 28 U.S.C. §§ 1332 and 1367, respectively.

6. This Court has personal jurisdiction over Provepharm because Provepharm has its principal place of business in New York and knowingly transacts a large volume of business in New York in the form of sales of pharmaceuticals, including methylene blue injection.

7. Venue is proper in this Court because this Court has personal jurisdiction over Provepharm. 28 U.S.C. § 1391(b) and 15 U.S.C. § 15(a).

FACTS COMMON TO ALL CLAIMS

The Market for Methylene Blue

8. These counterclaims involve the drug methylthioninium chloride, also known as methylene blue. Methylene blue is a medication, surgical stain, and contrast dye that is typically administered by injection into a vein of a patient. Methylene blue is an old drug. Indeed, it was the first fully synthetic drug used in medicine, first prepared in 1876 and first used in clinical treatment in 1891. It was one of the first antimalarial agents, and was widely used by Allied Forces to prevent malaria in troops deployed to the Southwest Pacific Theater during World War II. It has also been used as an intestinal and urinary antiseptic, as well as for treating methemoglobinemia. Methemoglobinemia is a fairly rare condition caused by elevated levels of methemoglobin in the blood. When a high level of methemoglobin, the oxidized form of hemoglobin, forms as a result of certain drugs or toxins in the blood, methylene blue is the antidote that converts it back to hemoglobin. Provepharm's NDA is directed to the treatment of methemoglobinemia and is the only FDA-approved use for methylene blue. Notwithstanding Provepharm's NDA, today methylene blue is used by healthcare providers for a multitude of unapproved indications, for example as an antidote for cyanide poisoning, and is often a component in other medications.

9. As is generally known, the Food and Drug Administration ("FDA") requires rigorous and specific tests to prove a new drug's effectiveness, and that even after approval,

drugs cannot be advertised or used without adhering to specific requirements. However, these requirements were not as strict until the FDA implemented its evidence-based approval system in 1938 where for the first time drugs had to be proven to be safe, and then amended again to prove effectiveness in 1962. *See* U. S. Food and Drug Administration/Center for Drug Evaluation and Research, *Guidance for FDA Staff and Industry, Marketed Unapproved Drugs – Compliance Policy Guide*, 2011, p. 9.

10. The 1938 legislation included a grandfather clause for pre-existing drugs meeting certain requirements, specifically "a drug product that was on the market prior to passage of the 1938 Act and which contained in its labeling the same representations concerning the conditions of use as it did prior to passage of that act was not considered a new drug and therefore was exempt from the requirement of having an approved new drug application." *Id.* at 11. Later, under the 1962 grandfather clause, "the FD&C Act exempt[ed] a drug from the effectiveness requirements if its composition and labeling has not changed since 1962 and if, on the day before the 1962 Amendments became effective, it was (a) used or sold commercially in the United States, (b) not a new drug as defined by the FD&C Act at that time, and (c) not covered by an effective application." *Id.* at 11–12 (citing Public Law 87-781, section 107 (reprinted following 21 U.S.C.A. 321) and *USV Pharmaceutical Corp. v. Weinberger*, 412 U.S. 655, 662-66 (1973)).

11. Up until 2016, all companies that manufactured and sold methylene blue did so under this "grandfather" status. Indeed, under this "grandfather" status, Akorn has sold its methylene blue products in the United States for decades.

Provepharm's Intent to Be the Sole Source of Methylene Blue

12. For purposes of the claims alleged herein, the relevant product market was—and is—the market for methylene blue. The relevant geographic market was—and is—the United States.

13. Drug manufacturers primarily compete against each other for sales. Drug manufacturers regard the availability and pricing of competitor products as directly affecting their pricing.

14. Provepharm's parent companies are based in France. Drug products marketed in France are subject to European Pharmacopoeia and ICH requirements and approval by the European Medicines Agency. During the 2000s, European regulatory bodies introduced stricter limitations for metal catalyst impurities than was required for methylene blue in the United States. Provepharm developed a process to manufacture a purer form of methylene blue that would comply with the stricter European limitations, and obtained several patents purportedly covering their manufacturing process for the purer form of methylene blue. *See* United States Patent Nos. 9,227,945, 8,765,942, and 8,815,850.

15. In 2011, Provepharm obtained approval from the European Medicines Agency to market its methylene blue product in Europe. At the same time, Provepharm engaged in discussions with regulatory and standard setting agencies in the United States to establish a monopoly over methylene blue products in the United States.

16. The first of Provepharm's parallel track strategy consisted of obtaining FDA approval of a New Drug Application ("NDA") for drug product in which methylene blue is the active pharmaceutical ingredient ("API"). Under the Food, Drug, and Cosmetic Act ("FDCA"), a sponsor seeking approval to market a new drug product may submit one of two forms of NDAs. A "full" NDA, submitted under Section 505(b)(1) of the FDCA, includes literature and studies performed by the sponsor or that the sponsor has the right to reference to demonstrate the safety and efficacy of the drug for the proposed indication. An NDA submitted under Section 505(b)(2), colloquially known within the industry as a "paper-NDA," relies on studies not conducted by or for the sponsor. Typically, an NDA under Section 505(b)(2) is only appropriate

where the API of the proposed drug product was previously approved as safe and effective in a prior NDA.

17. Although there was no pre-approved NDA in which methylene blue was the API, Provepharm submitted its NDA under Section 505(b)(2). Provepharm relied on the studies and data developed by others—including, in its own words, "the 150 year history of empirical usage of the product"—that demonstrated the safety and efficacy of methylene blue in the treatment of methemoglobinemia. Provepharm ultimately obtained FDA approval for ProvayBlue® on April 8, 2016.

18. When FDA approves an NDA or a supplement to an NDA, it may also award the sponsor of the NDA periods of exclusivity. For example, if an NDA describes a drug that contains a new chemical entity that was not previously in use in the United States, the FDA may grant New Chemical Exclusivity ("NCE"). When a new drug has NCE, the FDA will not accept, with certain exceptions, other NDAs having the same new chemical entity for a period of five years. Another example is New Product Exclusivity ("NPE"), which runs for three years, during which FDA will not approve another NDA if its relies on the same safety and efficacy data as the product that has NPE.

19. Provepharm's NDA for ProvayBlue® did not receive NCE or NPE. The only exclusivity it received was Orphan Drug Exclusivity ("ODE"). ODE is available to new drug products for which the approved indication is a disease or condition affecting fewer than 200,000 people in the United States, or if greater than 200,000 people, then there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. During ODE, which runs of seven years, FDA will not approve any other NDAs for the same API for the same condition. FDA may,

however, approve other NDAs for the same API if they are directed to other conditions and do not include the orphan condition.

20. Although Provepharm obtained approval for ProvayBlue® for this orphan drug designation, in fact the market for ProvayBlue® is all the uses of methylene blue.

21. Because FDA granted ProvayBlue® ODE for the treatment of pediatric and adult patients with acquired methemoglobinemia, FDA cannot approve any other NDAs for the use of methylene blue to treat pediatric and adult patients with acquired methemoglobinemia until April 8, 2023. However, FDA could approve other NDAs for the use of methylene blue for any other indication, including the numerous known conditions for which methylene blue had been used for more than a century.

22. Despite this, the second of Provepharm's parallel track strategy operated to foreclose any others from pursuing NDAs for the use of methylene blue for other indications. While Provepharm was obtaining approval from the FDA for ProvayBlue®, it was also soliciting the United States Pharmacopeia ("USP") to revise the official monograph for the API classified as methylene blue. On or about May 24, 2013, Provepharm requested that USP revise the criteria for methylene blue API and methylene blue injection, *i.e.*, a sterile solution of methylene blue in water for injection, to include the pentahydrate form of methylene blue—a different hydrate form of methylene blue that purportedly results from Provepharm's manufacturing process—and to change the standardized assay for other hydrate forms. *See* PROVEPHARM00000622.

23. The USP is a scientific nonprofit organization that sets standards for identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements that are manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the FDA. USP standards are recognized and required under federal law.

For example, the FDA enforces USP standards by requiring that any pharmaceutical product comply with the USP monograph for that drug product. *See* 21 U.S.C. § 351(b). Further, "[c]ompliance with a USP-NF monograph, if available, is mandatory."

24. When such medicines comply with the USP-NF standards, the products may be marketed and labelled as USP-compliant, generally by including "USP" after the product name (*e.g.*, "Methylene Blue Injection 1% USP"). That was how Akorn's methylene products were labeled because they complied at all times with the then-current USP-NF until Provepharm instigated the November 2016 changes.

25. As a public standards-setting organization, the USP has an express policy of impartiality and of not favoring one manufacturer over another in setting its standards. "USP will hold open meetings and publish standards impartially. USP will not provide . . . standards-setting activities, in a manner that will allow any stakeholder to have an undue advantage over another stakeholder." *See* USP Code of Ethics. "Consistent with and in furtherance of this mission, USP is committed to doing all it reasonably can to assure that USP-NF standards and related methods are developed through an objective, independent, science-based process, and that the resulting official compendial standards not have the effect of favoring any manufacturer over others or putting any FDA-approved product out of compliance. The USP attempts to maintain independence and impartiality, as it is critical to the integrity and credibility of its standard-setting activities." *See* USP Guideline for Submitting Requests for Revision to USP–NF, General Information for All Submissions.

26. To ensure impartiality and its policy of not favoring any one manufacturer over another, and "because USP's standards are intended to be public standards available for the use and benefit of all parties, USP requests that sponsors disclose in their Requests for Revision

whether any portion of the methods or procedures submitted is subject to patent or other sponsor-held intellectual property rights." *Id.*

27. On information and belief, Provepharm is familiar with these policies, having been advised by USP to review them. On information and belief, Provepharm confirmed it had reviewed the relevant materials relating to these policies.

28. Despite this, on information and belief, Provepharm violated clear USP rules and policies when it concealed the fact that Provepharm owned patents for the manufacturing process necessary to produce methylene blue in the form that Provepharm urged USP to adopt as its standard for methylene blue.

29. Moreover, on information and belief, Provepharm falsely asserted that the FDA required the inclusion of Provepharm's proposed methods and specifications. On information and belief, Provepharm failed to inform USP that the proposed methods and specifications "required" by the FDA were originally proposed by Provepharm. Further, on information and belief, Provepharm failed to inform USP that in order to meet the "required," proposed specifications using the proposed methods, a company would necessarily need to manufacture methylene blue API using manufacturing processes allegedly covered by Provepharm's patents.

30. On July 29, 2016, USP posted revisions for the methylene blue monographs, which required Provepharm's proposed specifications and assay testing method, and later adopted the revised monographs. Consequently, no other drug manufacturer can file an NDA having methylene blue API without producing the API in accordance with manufacturing processes allegedly covered by Provepharm's patents.

Provepharm's Conduct Achieved Monopolization

31. The net result of Provepharm's two-pronged attack was the effective monopolization of the market for methylene blue in the United States. Before Provepharm's

obtained approval for ProvayBlue®, Akorn and others could—and did—market methylene blue in the United States under the FDA's "grandfathered" status. After Provepharm obtained approval for ProvayBlue®, Akorn and others cannot market methylene blue in the United States unless they file and obtain approval of their own NDA or otherwise received exemptions from such requirements from FDA.

32. Before Provepharm successfully petitioned USP to revise the monographs for methylene blue and methylene blue injection, Akorn and others could have submitted their own NDAs for approval to market methylene blue without using manufacturing processes allegedly covered by Provepharm's patents. Although FDA granted Provepharm orphan drug exclusivity for the treatment of pediatric and adult patients with acquired methemoglobinemia, Akorn and others could have filed NDAs for other uses. Now, however, the USP monographs require manufacturing processes allegedly within the scope of Provepharm's patents. Thus, as a result of Provepharm successfully petitioning the USP to revise the monographs for methylene blue and methylene blue injection, Akorn and others cannot submit their own NDAs for approval to market methylene blue without risking being the subject of suits for patent infringement.

33. Akorn was forced to exit the market for its methylene blue in October of 2016, as they no longer conformed with the revised USP monograph, leaving Provepharm as the sole source of methylene blue in the United States and thus holding a monopoly in the relevant market. Alternatively, Provepharm obtained a dangerous probability of monopolizing the relevant market.

Harm to Akorn

34. Provepharm's harm to Akorn is two-fold. First, the change instigated to the methylene blue USP removed Akorn's methylene blue product from the market earlier than what would have occurred had Provepharm only obtained an approved NDA. When there are

grandfathered products on the market, and a new NDA is approved for the API used in those products, the FDA expects for the grandfathered products to either obtain their own NDA approvals or for the market to otherwise transition to the new NDA-approved product. This transition period can range between six and twelve months, during which time the grandfathered products continue to have significant sales.

35. The supply of Akorn's methylene blue products was, however, abruptly disrupted by the changes Provepharm instigated in the USP monographs. To manufacture drug products—even grandfathered products—Akorn must have a "standard" against which to verify its new batches.

36. After Provepharm instigated the change to the USP monographs, Akorn could not use the original standard to which its grandfathered methylene products conformed. Therefore, Akorn could not manufacture and sell additional units of methylene products. It was forced to exit the market in October of 2016 and remained so until June 2017, when the FDA permitted Akorn to temporarily manufacture methylene blue using the expired USP standard. Akorn lost out on months of sales during which time it would have been supplying most of the methylene blue market. During those approximate ten months, Provepharm's anticompetitive conduct achieved actual monopolization in fact.

37. Notwithstanding the introduction of ProvayBlue®, there remained—and remains to this day—demand for Akorn's methylene blue products. Therefore, when FDA permitted Akorn to resume manufacturing and selling methylene blue products qualified against the expired original standard, Akorn did so, and has re-entered the market, but at a substantially reduced market share that is artificially lower than would have occurred had Provepharm not instigated the change to the USP monographs.

38. Akorn's re-entry into the methylene blue market is also temporary. FDA permitted Akorn to manufacture methylene blue products qualified against the expired original standard, which Akorn did. In the process, however, Akorn exhausted its supply of the expired original standard. As a result of Provepharm instigating the change to the USP monographs, additional quantities of the expired original standard are no longer available. Consequently, even if FDA continues to request it, Akorn cannot manufacture additional methylene blue products. Therefore, once Akorn exhausts its on-hand supply of methylene blue products, it will once again be forced from the market, and Provepharm will have once again achieved monopolization of the methylene blue market.

FIRST COUNTERCLAIM OF AKORN
(Actual Monopolization)

39. Akorn incorporates by reference all allegations contained in each of the above paragraphs of the Counterclaim herein by reference.

40. Provepharm's anticompetitive conduct set forth in this Counterclaim violates Section 2 of the Sherman Act. *See* 15 U.S.C. §2.

41. As a result of Provepharm's anticompetitive conduct, Provepharm excluded Akorn from the methylene blue market.

42. As a result of Akorn's exclusion from the methylene blue market, Akorn was unable to sell methylene blue products for several months, and even on its return to the methylene blue market, has suffered diminished sales of methylene blue products, resulting in substantial damages.

43. Provepharm's actions were a material and substantial contributing factor to injuries to Akorn, but for which Akorn would not have been damaged in an amount that remains to be determined.

SECOND COUNTERCLAIM OF AKORN
(Attempted Monopolization)

44. Akorn incorporates by reference all allegations contained in each of the above paragraphs of the Counterclaim herein by reference.

45. Provepharm has attempted to monopolize the relevant market in violation of Section 2 of the Sherman Act based on the anticompetitive conduct described herein.

46. Provepharm had a specific intent to monopolize the relevant market. As discussed in more detail above, Provepharm purposefully acted to wrongfully block anyone else, including specifically Akorn, from selling methylene blue in the United States.

47. Through the anticompetitive and exclusionary acts described above, Provepharm achieved a dangerous probability of success of monopolizing the relevant market. By excluding Akorn and others, Provepharm will maintain monopoly over the methylene blue injection USP in the United States. As a result of being blocked from selling methylene blue, Akorn will suffer antitrust injury.

48. Provepharm's actions were a material and substantial contributing factor to injuries to Akorn, but for which Akorn would not have been damaged in an amount that remains to be determined.

PRAYER FOR RELIEF

Wherefore Akorn prays for the following:

A. An award of damages under 15 U.S.C. § 5, including treble damages, costs, and reasonable attorneys' fees;

B. Injunctive relief under 15 U.S.C. § 26 barring Provepharm from engaging in further conduct that threatens loss or damage by a violation of the antitrust laws of the United States; and

C. Such further relief as this Court may deem just and equitable.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Akorn hereby demands a trial by jury on its counterclaims.

Dated: New York, New York
August 27, 2018

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